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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,792	06/13/2001	Yonghong Xiao	02973.00035	3733

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BANNER & WITCOFF  
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WASHINGTON, DC 20001

EXAMINER

RAMIREZ, DELIA M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

44

**Advisory Action**

**Application No.**

09/879,792

**Applicant(s)**

XIAO ET AL.

**Examiner**

Delia M. Ramirez

**Art Unit**

1652

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 22 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 1-15,22-24 and 69-71.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 74-77,79-81,83-85.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

***ADVISORY ACTION***

1. Claims 1-15, 22-24, 69-71, 74-77, 79-81, 83-85 are pending.
2. The period for reply continues to run from the date of the final rejection. Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a) accompanied by the appropriate fee. The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. A reply within the meaning of 37 CFR 1.113 must be timely filed to avoid abandonment of this application.
3. The request for entering amendments to claims 9-10, 14-15, 24, 69, 74-77, 79-81, 83, addition of claims 84-85, cancellation of claims 78, 82, and arguments filed on 10/22/2003 under 37 CFR 1.116 in reply to the Final Action Paper No. 15 mailed on 8/12/2003 are acknowledged. The proposed amendments to the claims will be entered since they are deemed sufficient to overcome objections and the 112, second paragraph rejections previously applied. However, entry of these amendments is not deemed sufficient to place the application in condition for allowance for the following reasons.
4. Claims 74-77, 79-81, 83-85 as amended would be rejected under 35 USC 112, second paragraph in view of the recitation in claims 74-75, 84-85 (claims 76-77, 79-81, 83 dependent thereof) of “polynucleotide... that hybridizes...to the nucleotide sequence..” for the following reasons. As known in the art, hybridization occurs among molecules. Sequences are graphical representations of the order in which nucleotides are arranged in a nucleic acid. This rejection would be overcome by amending the claims to recite, for example, “polynucleotide...that hybridizes...to the polynucleotide of...”.
5. While Applicants submit that the claims as amended are adequately described, claims 74-77, 79-81, 83-85 would remain rejected under 35 USC 112, first paragraph, written description. The Examiner agrees that the first polynucleotide as recited in claims 74 and 75, i.e. consisting of at least 300 contiguous nucleotides of the complete complement of the polynucleotide of SEQ ID NO: 11, would be adequately described. However the claims as amended are also directed to genera of polynucleotides of any function

Art Unit: 1652

comprising at least 300 or 450 nucleotides, wherein said polynucleotides are 70-98% structural (i.e. sequence) homologs of the polynucleotide of SEQ ID NO: 11 or the cDNA insert in plasmid pCRII-TMSP3. As indicated in previous Office Action Paper No. 15, mailed on 8/12/2003, while the claims recite the term "probe", there is no limitation in regard to the biological function of such polynucleotides. The claims, while encompassing polynucleotides of any function, are not adequately described since the specification fails to disclose other functions for the claimed genera of polynucleotides, does not disclose the critical structural elements required in any polynucleotide to encode a polypeptide having the only function disclosed, nor does it disclose which 300 or 450 nucleotides in the polynucleotide of SEQ ID NO: 11 are essential to encode a serine protease.

6. Claims 74-77, 79-81, 83-85 would remain rejected under 35 USC 112, first paragraph, scope of enablement. While Applicants submit that the claims as amended are enabled since (1) the genera of polynucleotides claimed is not as broad as asserted by the Examiner, (2) only one disclosed use need to be enabled, (3) the claimed polynucleotides do not have serine protease activity, and (4) the claimed polynucleotides are complementary to coding sequences and do not encode a protein, these arguments are not found persuasive since the claims as amended are directed to polynucleotides of any function comprising at least 300 or 450 nucleotides, wherein said polynucleotides are 70%-98% structural homologs of the polynucleotide of SEQ ID NO: 11 or the cDNA insert in plasmid pCRII-TMSP3. As indicated above, the specification is silent in regard to all the functions associated with the polynucleotides encompassed by the claims nor does it provide any information as to the critical structural elements required in any of the claimed polynucleotides to encode a polypeptide having the only function disclosed, i.e. serine protease activity. In addition, the specification does not teach which 300 or 450 nucleotides are required in the claimed polynucleotides to encode a protein with the only function disclosed, i.e. essential for serine protease activity. It is noted that when the Examiner refers to activity in regard to polynucleotides, it is in reference to the biological function of the polypeptide

Art Unit: 1652

encoded by such polynucleotides. Therefore, the Examiner is not contending that polynucleotides have serine protease activity but rather they encode proteins which can have such activity. In addition, while it is agreed that only one disclosed use need to be enabled, it is noted that such use has to be a patentable use (i.e. utility). Therefore, while the polynucleotide of SEQ ID NO: 11 has been found to have patentable utility, the use recited in the instant claims, i.e. probes, for the remainder of species in the genera of polynucleotides claimed is not found to be specific and substantial and does not meet the "how to use" requirement under 35 USC 112, first paragraph. In regard to arguments that the claimed polynucleotides do not encode any protein because they are complements of coding polynucleotides, it is noted that (1) the term "polynucleotide" unless specifically indicated, refers to a double stranded nucleic acid, and (2) there is no recited limitation in the claims which exclude any coding polynucleotide. As such, coding and noncoding polynucleotides are encompassed by the claims.

7. Claims 74-77, 79-81, and 83 were previously rejected under 35 USC 102(b) as being anticipated by Dias Neto et al. Since the polynucleotide of Dias Neto et al. comprises 285 contiguous nucleotides of the polynucleotide of SEQ ID NO: 11, and in view of the fact that the amended claims are no longer directed to polynucleotides comprising at least 225 contiguous nucleotides of the polynucleotide of SEQ ID NO: 11, this rejection is hereby withdrawn.

8. For purposes of Appeal, the status of the claims is as follows:

Claim(s) allowed: 1-15, 22-24, 69-71

Claims(s) objected to: NONE

Claim(s) rejected: 74-77, 79-81, 83-85

Claim(s) withdrawn from consideration: NONE

9. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
November 7, 2003

  
